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Patent
Q101

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

IN RE APPLICATION OF:
CHU ET.AL.

SERIAL NO. : 09/430,050

FILED: OCT. 29, 1999

FOR: SPLIT VALVE FOR PEEL-AWAY SHEATH



**PROTEST**
**37 CFR 1.291**

Hon. Commissioner of Patents and Trademarks
Washington DC 20231

Sir:

Based on the published PCT patent application, WO 01/32257 A1 we believe that SciMed Life Systems Inc., the assignee of the above application, seeks claims in the United States Patent and Trademark Office, which incorporate the elements of two previously issued U.S. Patents listed below.

These claims are protested in that they are overbroad, claim at least in part combinations which are in the prior art, and fail to clearly distinguish in Jepson form over the issued U.S. Patents listed below.

*Listing of Patents – 37 CFR 1.291(b)(1)*

If such an application was filed, it may have claims which are anticipated or obvious over **Lee**, U.S. Patent B1 5,125,904 and **Lee**, U.S. Patent 5,312,355, copies of which are enclosed as required by *37 CFR 1.291(b)(3)*.

*Concise Explanation of Relevance of Patents – 37 CFR 1.291(b)(2)*

The **Lee** patents are relevant to the **Chu** combination for the subject matter set out in their claims. In particular the **Lee** patents teach a hemostatic valve with an infusion side arm, which valve is coupled to a peel-away introducer. In other words, the valve has a housing with a compression or self-healing membrane or seal, which is closed over or positioned adjacent to the proximal end of the peel-away introducer. The housing and its sealing membrane form a fluid and air tight temporary seal around the lead or catheter disposed through the hemostatic valve and introducer. When it is desired to remove the valve, the valve halves are separated, withdrawing the housing from the lead or catheter without the need of sliding it over the end of the lead or catheter.

(a) **Lee**, U.S. Patent B1 5,125,904

Claim 1 calls for a "means for permitting removal of said hemostatic valve and introducer sheath from said lead or catheter disposed therethrough without requiring said introducer sheath and hemostatic valve to be removed from an end of said lead or catheter." The means in the illustrated embodiment is shown as a

break or tear line continuously led from the introducer to the valve. Col. 5, line 40 –55, provides:

> "The detailed construction of sheath 12 and valve assembly 14 as previously implied is not critical to the invention, at least to the extent of whether sheath 12 and valve assembly 10 must be separate or integral parts or how they may be connected with each other. Therefore, it must be expressly understood that valve assembly 14 and sheath 12 may be fabricated according to any structure or out of any material now known to the art or later devised without departing from the spirit and scope of the invention. For example, sheath 12 may be integrally molded or cast with valve assembly, may be adhesively affixed thereto, may be compression fitted, slip fit, threaded, or connected in any manner desired to valve assembly 14 consistent with the teachings of the present invention."

The "means" as disclosed in the specification is thus broadly enabled with respect to the type of connection between the valve housing and the sheath or introducer.

Claims 2 – 9 deal with the means of permitting removal of the valve and sheath. Reexamined claim 9 is the first instance in the claim chain where the removal of the introducer and valve housing must occur together as an integral unit. Hence, it can thus be concluded that claims 1 – 8 do not require the introducer and valve housing to be removed together as an integral unit and thus are relevant to the **Chu** combination.

Claim 10 depends on claim 1 and calls for a self-healing valve; claim 11 depends on claim 1 and calls for use with multiple leads.

Claim 12 calls for the introducer sheath and hemostatic valve to be separate body portions coupled to each other and the means for permitting

removal of the valve and sheath to allow separate removal of the hemostatic valve and sheath from the lead or catheter.

Claims 13 – 17 are method claims that include the use of a sidearm in combination with a separable valve and sheath.

Claim 18 calls for splitting of the introducer and separating the valve assembly independently from each other. The nature of the "splitting" or "separating" is broadly enabled in the specification at col. 5, lines 56 – 66, wherein it states:

> "According to the invention, both valve assembly 14 and sheath 12 are splittable or have a peel away construction. Again, the detailed nature by which such splittable structure is implemented or how peel-away feature is realized is not critical to the invention. Any method now known or later devised by which such sheaths 12 and valve assemblies 14 may be split or separated may be employed and are contemplated as being within the scope of the invention."

Claim 18 distinguishes between how the valve is removed and how the introducer is removed.

Claim 19 calls for separate removal of the introducer and valve without characterizing the "removal" in more specific terms.

Reexamined claims 20 – 22 call for an over-the-guidewire assembly without any specific limitation on the means for splitting or the removal of the introducer and valve together.

Reexamined claim 23 calls for a peel-away valve housing using guidewire placement. Claims 24 call for a peel-away membrane, claim 25 introduces for the first time into the claim chain simultaneous removal and claim 26 calls for separate removal.

Reexamined claim 27 calls for a through-the-needle placement of the lead or catheter without any specific limitation on the means for splitting or the removal of the introducer and valve together. Claim 28 calls for a dilator. Claim 29 refers to an over-the-needle placement.

Reexamined claims 30 – 33 call for a through-the-needle placement of the lead or catheter with a peel away valve housing.

Reexamined claim 34 calls for an over-the-guidewire system and a peel-away valve housing.

(b) **Lee**, U.S. Patent 5,312,355

Claims 1 and 19 call for a removable hemostatic valve coupled to an introducer sheath in which the hemostatic valve allows a lead or catheter to be disposed through it, and a means for permitting removal of the hemostatic valve from the lead or catheter without requiring the introducer sheath and hemostatic valve to be removed from an end of the lead or catheter. The means for permitting removal of the hemostatic valve comprises a two-part body made in two separate body portions which define means for sealing the body portions together when the two body parts are joined with each other to form the hemostatic valve. This teaching is believed to be relevant to the **Chu** combination.

Claims 2 and 3 refer to a resealable membrane and a cut in the resealable membrane to facilitate parting of the membrane wherein the body portions are pulled apart. This teaching is believed to be relevant to the **Chu** combination.

Claims 4 – 13 refer to various arrangements of a circumferential sealing lip on each of the body portions to make the hemostatic valve fluid-tight wherein the body portions are temporarily joined together. This teaching is believed to be relevant to the **Chu** combination.

Claim 14 is directed to a method of percutaneous catheterization including the step of removing the hemostatic valve while leaving the lead or catheter in place within the body lumen without sliding the hemostatic valve over an end of the lead or catheter, where the hemostatic valve is comprised of two body portions which are separately provided to form the hemostatic valve and are temporarily joined together to form a complete body of the hemostatic valve, and wherein the body portions are pulled apart to split the hemostatic valve. This teaching is believed to be relevant to the **Chu** combination.

Claims 15 – 17 refer to various methods of splitting or prying apart the valve along a longitudinal length of the valve and disposing the lead or catheter radially through the longitudinal split.

Claims 21 and 22 depend on directly or indirectly on claim 19 and is directed to a hemostatic valve having a releasable membrane and a cut in the releasable membrane to facilitate parting of the membrane wherein the body portions are pulled apart.

Claims 23 – 31 are directed to various forms of a circumferential sealing lip one each of the body portions to make the hemostatic valve fluid-tight wherein the body portions are temporarily joined together.

Claims 32 and 33 are directed to an exterior fastening means to temporarily maintain the body portions together. This teaching is believed to be relevant to the **Chu** combination.

*Application of the Lee Patents to the Chu Claims*

The pending **Chu** claims are as follows. Portions underlined represent elements which are believed to the be same as or might be argued by **Chu** to be equivalent to corresponding elements in the **Lee** patents by reason of overbreadth and/or lack of distinguishing definition in the claims as submitted.

> 1. A valve for a tubular peel-away sheath having a lumen therethrough comprising:
> a valve body having a lumen therethrough;
> means for preferentially breaking said valve body along a predetermined location in response to applied force, such that said valve body lumen splits open upon breaking;
> means for coupling said valve body to said peel-away sheath for coupling said peel-away sheath lumen to said valve body lumen;
> means for receiving a compressible valve sleeve having a lumen therethrough for coupling said valve sleeve lumen to said valve body lumen; and
> means for compressing said valve sleeve for restricting any fluid flow from said peel-away sheath lumen through valve and valve sleeve lumen.

*Comment*

The **Lee** patents disclose the combination of a splittable valve (i.e. valve sleeve), valve housing (i.e. valve body) and sheath through which a catheter is disposed. The valve is inherently compressed within and by the valve housing, which inherently serves as a means for compressing. The valve, when left in its

normal compressed configuration restricts fluid flow through from the sheath through the valve and valve housing.

In particular, the **Lee** patents disclose a valve device for a tubular peel-away sheath having a lumen therethrough. The valve housing has a lumen therethrough. A means is provided for preferentially breaking the valve housing along a predetermined location in response to applied force, such that the valve housing lumen splits open upon breaking. The valve housing is coupled to the peel-away sheath to couple the peel-away sheath lumen to the valve body lumen. The valve housing receives a compressible valve having a lumen therethrough for coupling the valve lumen to the valve housing lumen. The valve housing compresses the valve to restrict any fluid flow from the peel-away sheath lumen through valve housing and valve lumens.

> 2. A valve as recited in claim 1, wherein said valve sleeve includes a free end extending past said means for compressing, and further comprising means for receiving a catheter tip within said valve sleeve lumen free end while said means for compressing is compressing said valve sleeve, such that said valve sleeve lumen is substantially occluded by said inserted catheter tip while said catheter tip is inserted.

*Comment*

The **Lee** patents disclose a valve which receives a catheter tip within the valve sleeve lumen while the valve body compresses the valve, such that the valve lumen is substantially occluded by the inserted catheter tip while the catheter tip is inserted.

> 3. A breakaway valve for a tubular peel-away sheath, said sheath having an external surface, a lumen, and a proximal end comprising:

means for reversibly restricting fluid flow from said sheath lumen coupled to said sheath proximal end;

means for breaking apart said fluid flow restricting means responsive to applied force; and

means for admitting a catheter distal end into said valve.

*Comment*

The **Lee** patents disclose a breakaway valve device for a tubular peel-away sheath in which the sheath has an external surface, a lumen, and a proximal end. The valve restricts fluid flow from the sheath lumen coupled to the sheath proximal end. The valve body breaks apart the valve responsive to an applied force. The valve body and valve admits a catheter distal end into the valve.

4. A breakaway valve as recited in claim 3, wherein said means for reversibly restricting flow has an open position for allowing flow therethrough and a closed position for substantially restricting flow, wherein said means for admitting said catheter distal end includes means for admitting said catheter distal end while said means for restricting flow is in said closed position.

*Comment*

The **Lee** patents disclose a breakaway valve as recited in claim 3, wherein the valve for restricting flow has an open configuration for allowing flow therethrough and a closed configuration for substantially restricting flow, wherein the valve housing may admit the catheter distal end while the valve still restricts flow by reason of its closed configuration.

5. A breakaway valve as recited in claim 4, wherein said means for restricting flow includes a flexible, constrictable tube having a lumen therethrough.

*Comment*

The **Lee** patents disclose a breakaway valve as recited in claim 4, wherein the valve for restricting flow includes a flexible, constrictable tubular member having a lumen therethrough.

> 6. A breakaway valve as recited in claim 5, wherein said means for restricting flow includes means for pinching said flexible tube for constricting said flexible tube lumen.

*Comment*

The **Lee** patents disclose a breakaway valve as recited in claim 5, wherein said valve for restricting flow is compressed or pinched by the valve housing to constricting said flexible tube lumen or valve.

> 12. An introducer sheath assembly for introducing a catheter distally into a human body comprising:
>
> a tubular, distal introducer sheath having a proximal region and a lumen therethrough, said sheath having at least one longitudinal strip for preferentially tearing said sheath along said strip;
>
> a tubular, flexible, proximal valve sleeve having a proximal region, a distal region, and a lumen therethrough; and
>
> a valve body having a lumen therethrough and being sealingly coupled to said introducer sheath proximal region, said valve having at least one weakened region for preferentially splitting said valve into at least two pieces responsive to an applied breaking force, said valve body having a seat for mating to said proximal valve sleeve distal region, said valve body including a pinch member for pinching said flexible valve sleeve and having a closed position for constricting fluid flow through said valve sleeve and an open position for admitting a catheter inserted through said valve sleeve.

*Comment*

The **Lee** patents disclose an introducer sheath assembly for introducing a catheter distally into a human body. A tubular, distal introducer sheath is shown having a proximal region and a lumen therethrough. The sheath has at least one longitudinal strip for preferentially tearing the sheath along the strip. A tubular, flexible, proximal valve has a proximal region, a distal region, and a lumen

therethrough. A valve housing has a lumen therethrough and is sealingly coupled to the introducer sheath proximal region. The valve and valve housing have at least one weakened region for preferentially splitting the valve and valve housing into at least two pieces responsive to an applied breaking force. The valve housing has a seat for mating to the proximal valve distal region. The valve housing pinches or compresses the flexible valve, which has a closed configuration for constricting fluid flow through the valve and an open configuration for admitting a catheter inserted through the valve.

15. A breakaway valve body for restricting flow from a peel-away introducer sheath having a proximal region and a lumen therethrough comprising:

a breakaway distal portion having a lumen therethrough for receiving said introducer sheath proximal region; and

a proximal portion including two opposed valve body members, at least one of which is movable relative to the other and having concave surfaces therebetween for receiving a flexible valve sleeve therebetween, said valve body opposed members having an open position and a closed position, wherein said valve body members move apart relative to each other to reach said open position and said valve body opposed members move together relative to each other to reach said closed position, wherein said flexible sleeve has a lumen therethrough and said sleeve and sleeve lumen are constricted between said body members in said closed position, such that fluid flow through said sleeve is substantially restricted in said closed position.

*Comment*

The **Lee** patents disclose a breakaway valve housing for restricting flow from a peel-away introducer sheath having a proximal region and a lumen therethrough. The a breakaway distal portion of the valve housing has a lumen therethrough for receiving the introducer sheath proximal region. The valve housing also has a proximal portion including two opposed valve housing walls for receiving a flexible valve therebetween. The valve has an open and a closed

configuration, wherein the valve includes portions which move apart relative to each other to reach the open configuration and move together relative to each other to reach the closed configuration. The flexible valve has a lumen therethrough and the valve and valve lumen are constricted between the walls of the valve housing in the closed configuration, such that fluid flow through the valve is substantially restricted.

18. A breakaway valve body as recited in claim 16, wherein said valve body members have a proximal end and said valve body members include at least one pinch member for pinching said flexible sleeve therebetween and said pinch member is disposed distally of said valve body proximal end such that a proximal region of said valve body and a proximal region of said flexible sleeve can have a catheter inserted therein while said valve body members are in said closed position.

*Comment*

The **Lee** patents disclose a breakaway valve body, wherein the valve housing has a proximal end and pinch or compress the flexible valve therebetween.

19. A breakaway valve body as recited in claim 18, wherein said valve body members have a proximal end and said valve body members include at least one pinch member for pinching said flexible sleeve therebetween and said pinch member is near said valve body proximal end, wherein said flexible sleeve includes a proximal region extending proximally of said pinch members such that a proximal region of said flexible sleeve can have a catheter inserted therein while said valve body members are in said closed position.

*Comment*

The **Lee** patents disclose a breakaway valve body, wherein the valve housing walls have a proximal end and pinch or compress the flexible valve therebetween.

23. A breakaway valve body for restricting flow from a peel-away introducer sheath having a proximal region and a lumen therethrough comprising:

a breakaway distal portion having a lumen therethrough for receiving said introducer sheath proximal region; and

a proximal portion including a first valve body member and a second valve body member opposed to said first body member for receiving a flexible valve sleeve therebetween, wherein said first valve body member has a proximal region and a concave inner surface and said second valve body member has an arm hingedly mounted to said first valve body member proximal region and said arm includes an inner pinch member for pressing inward toward said first body member, wherein said arm has a distal ratchet end for mating to a series of notches on said valve body for holding said arm and pinch member in a series of increasingly constrictive pinching positions against said inserted valve sleeve.

*Comment*

The **Lee** patents disclose a breakaway valve housing for restricting flow from a peel-away introducer sheath having a proximal region and a lumen therethrough. A breakaway distal portion of the valve housing has a lumen therethrough for receiving said introducer sheath proximal region. A proximal portion of the valve housing includes two opposing housing walls for receiving a flexible valve therebetween.

*Conclusion*

The applicant's claims should be amended to distinguish over the issued U.S. Patents listed above and the distinguishable elements, if any, be clearly delineated from the previously disclosed and claimed combinations in the prior art.

Respectfully submitted,

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PROOF OF SERVICE

I hereby certify that a true and correct copy of the Protest was deposited with the United States Postal service, first class postage prepaid, addressed to:

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Minneapolis, MN 55401-2246



Date: 25 May 2001

BERNADETTE M. CASTRO